IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	**Group Art Unit:** TBA
Berg et al.	**Examiner:** TBA
Serial No: 09/245,939	**Atty Docket No.:** 97-195P
Filed: July 9, 2001	
For: Improved Nucleic Acid Assays	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please enter this preliminary amendment before substantive examination of this application. It is believed that no fee is due in connection with this filing. However, if a fee is due the Commissioner is authorized to charge our Deposit Account No. 13-2490.

IN THE SPECIFICATION:

On page 25, please replace the first full paragraph with the following paragraph:

> Other examples of reaction vessels and amplification station components are also envisioned, and certain examples of such alternative embodiments are described in copending U.S. patent application of Luigi Catanzariti et al., serial no. 08/850,207 (now U.S. Pat. No. 5,786,182) hereby incorporated by reference in the entirety.

IN THE CLAIMS:

Please delete claims 2-9 and add the following new claims:

10. A method for the detection of the presence or absence of a single stranded or double stranded first nucleic acid in a test sample, by automated isothermal amplification of said first

nucleic acid, said method performed in at least two reaction vessels which can be placed in fluid communication with each other, said method comprising:

a) combining in a first reaction vessel; a test sample and reagents suitable for carrying out a nucleic acid amplification reaction such that a reaction mixture can form and placing said reaction vessel in an automated apparatus such that:

b) the automated apparatus heats said first reaction vessel to a sufficient temperature, and for a sufficient time to render any double stranded first nucleic acid in said sample to be tested into sufficient single stranded nucleic acid available for hybridization,

c) the automated apparatus cools said first reaction vessel to a sufficient temperature to form a hybridization product, said hybridization product comprising at least one oligonucleotide primer and a first nucleic acid if said first nucleic acid is present in said test sample,

d) contacting said product from said first reaction vessel with a nucleic acid amplification enzyme to provide a nucleic acid amplification mixture and transferring said amplification mixture to a second reaction vessel,

e) amplifying said first nucleic acid wherein the automated apparatus maintains the temperature of said second reaction vessel at a sufficient temperature which allows for a specific oligonucleotide primer mediated amplification of said first nucleic acid to produce amplicons, and

f) detecting the presence of amplicons.

11. The method according to claim 10 further comprising capturing said amplicons with a nucleic acid capture probe bound on a solid support such that a capture probe hybridization complex is formed.

12. The method according to claim 11 further comprising contacting said capture probe hybridization complex with a labeled nucleic acid probe specific for said amplicons such that a labeled probe complex is formed.

13. The method according to claim 12 further comprising contacting said labeled probe complex with a substrate to generate a detectable signal whereby said signal is proportional to the amount of said first nucleic acid in said test sample.

14. The method according to claim 10 wherein said reagents comprise a reaction buffer, a mixture of free nucleotides, or at least one oligonucleotide primer.

15. The method according to claim 10 wherein said apparatus transfers said reaction mixture from said first reaction vessel to a second reaction vessel containing said nucleic acid polymerization enzyme, such that said reaction mixture is brought into contact with said nucleic acid amplification enzyme in said second reaction vessel.

16. The method according to claim 10 wherein said apparatus transfers said nucleic acid amplification enzyme contained in said second reaction vessel to said first reaction vessel, such that said nucleic acid polymerization enzyme is brought into contact with said reaction mixture.

17. The method according to claim 11 wherein said solid support is a pipette-like device.

18. The method according to claim 11 wherein said solid support is controlled by an automated apparatus.

19. The method according to claim 11 further comprising washing said capture probe hybridization complex bound on said solid support such that non-specifically bound amplicons and nucleic acids are washed away from said solid support.

20. The method according to claim 12 further comprising washing said labeled probe complex such that non-specifically bound amplicons and labeled nucleic acid probes are washed away from said solid support.

21. The method according to claim 10 wherein said automated apparatus displays a value for said signal and optionally records a value for said signal.

22. The method according to claim 10 wherein said nucleic acid amplification enzyme is loaded in said second reaction vessel as a lyophilized pellet in single assay or unit dose amount.

23. The method according to claim 22 wherein said second reaction vessel is sealed prior to use.

24. The method according to claim 16 wherein said enzyme is brought into contact with said reaction mixture during the transfer process.

25. The method according to claim 10 wherein said amplification mixture is transferred to said second reaction vessel through a fluid channel, said fluid channel comprising a valve which operates to allow fluid to flow between said vessels.

26. The method according to claim 25 wherein said valve is a thimble valve.

Remarks

The specification has been amended to incorporate the serial number and patent number of a referenced application. A marked-up copy of the amended paragraph appears in Appendix A. No new matter is added by this amendment. Applicants respectfully request entry of the amendment.

Respectfully submitted,

Dated: 7-9-01

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APPENDIX A

Version with Markings to Show Changes Made

Other examples of reaction vessels and amplification station components are also envisioned, and certain examples of such alternative embodiments are described in copending U.S. patent application of Luigi Catanzariti et al., serial no.[_____] 08/850,207 (now U.S. Pat. No. 5,786,182) hereby incorporated by reference in the entirety.